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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/616,900	07/09/2003	Julie Sudduth-Klinger	2300-15805CON	5219

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EXAMINER	
SMITH, CAROLYN L	

ART UNIT	PAPER NUMBER
1631	

DATE MAILED: 10/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/616,900	SUDDUTH-KLINGER ET AL.	
	Examiner	Art Unit	
	Carolyn L. Smith	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 August 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-22* is/are pending in the application.

4a) Of the above claim(s) *1-5 and 9-22* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *6-8* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *09 July 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicants' election with traverse of Group II (claims 6-8), filed 8/16/06, is acknowledged. Claims 1-5 and 9-22 are withdrawn from consideration as being drawn to non-elected Groups.

Applicants' traversal is on the grounds that Groups II and IV are related in that the assessing the tumor burden of a subject (Group IV) requires the assessment of a cancerous phenotype (Group II).

The Applicants' request to combine Groups II and IV into one invention was found unpersuasive because of the following reasons (summarized from the restriction paper):

The methods of groups II and IV achieve different goals. Group II assesses a cancerous phenotype specifically for colon. Group IV assesses a general tumor burden in a subject. These inventions can have a materially different design, mode of operation, function, or effect. These distinct methods are often separately characterized and published in literature and would add undue search burden if they were examined together. Thus, they are considered distinct invention types for restriction purposes.

The requirements are still deemed proper and are therefore made FINAL.

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. The present title is directed to gene products differentially expressed in cancerous colon cancer cells and their methods of use, whereas in contrast the elected claims are specifically directed to a method for assessing the cancerous phenotype of a colon cell.

The drawing, filed 7/9/03, is accepted by the Examiner.

Claims herein under examination are 6-8.

Claim Rejections – 35 U.S.C. 112, first paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized in *Ex parte Forman*, 230 USPQ 546 (BPAI 1986) and reiterated by the Court of Appeals in *In re Wands*, 8 USPQ2d 1400 at 1404 (CAFC 1988). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. The Board also stated that although the level of the skill in molecular biology is high, the results of experiments in genetic engineering are unpredictable. While all of these factors are considered, a sufficient amount for a *prima facie* case are discussed below.

LACK OF ENABLEMENT

Claims 6-8 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the claimed invention.

Claim 6 recites assessing a cancerous phenotype of a colon cell via detecting expression of a gene product in a test colon cell sample and comparing it to the expression level of a gene product expression in a control cell sample. Claim 6 recites that the comparison is "indicative of the cancerous state of the test cell sample". One of skill in the art would not be able to draw such conclusions for various reasons. First, the control cell sample as stated in instant claim 6 is not necessarily from colon. A person of skill in the art would not be able to make sound conclusions while comparing a control sample from a different organ, such as the heart, to the test sample from colon. Also, comparing expression levels alone does not necessarily indicate the cancerous state of a test sample. Any variation between a test sample and control sample may be due to random sampling error. Without knowing whether a difference in the comparison was statistically significant, a person of skill in the art could not reasonably conclude that a comparison indicates a cancerous state.

The specification on page 46 (Example 1 and Table 1) states that various cell lines and patient tissue have been tested, including those from colon, breast, and lung, and it is not readily apparent from the instant specification where the control sample is coming from. The gene recited in this method is identical to a sequence from GenBank (accession numbers XM_007326) that is from Homo sapiens bone morphogenetic protein 4 (BMP4) mRNA (Table 3). There are millions of sequences in the world with a small portion actually available in public databases, such as GenBank. A microarray type of invention that involves a sequence originating from various types of organs and a particular function not associated with colon cancer does not appear to be enabling as allegedly being indicative of a cancerous state of a test sample, as stated in instant claim 6. This lack of enablement is also an issue because the control is not necessarily

from a colon sample and the sequence appears to have functions related to bone formation instead of indicating colon cancer. The quantity of experimentation required to verify that SEQ ID NO: 22 represents a valid indicator of a cancerous state of a test colon cell sample appears to be undue.

Due to undue experimentation required, lack of guidance directed to verifying that SEQ ID NO: 22 is a valid colon cancer indicator when compared to any type of control, the lack of working examples addressing the same, and the breath of the claims; this invention is rejected due to the lack of enablement for one skilled in the art to be able to make and use the invention. Claims 7 and 8 are also rejected due to their dependency from claim 6.

Claims Rejected Under 35 U.S.C. § 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 6-8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention.

The preamble of claim 6 recites assessing the cancerous phenotype of a colon cell; however the method steps do not recite any phenotypic limitations. Therefore, it is unclear if the preamble or the body of the claim is controlling the metes and bounds of the claim. Clarification

of this issue via clearer claim wording is requested. Claims 7 and 8 are also rejected due to their dependency from claim 6.

Claims 7 and 8 (line 1 of each) recite the limitation "expression of the gene". There is insufficient antecedent basis for this limitation in these claims. While there is previous mention of expression of a gene *product*, there is no previous mention of expression of a *gene*.

Claim Rejections – 35 USC §102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 6-8 are rejected under 35 U.S.C. 102(e) as being anticipated by Au-Young et al. (US 6,500,938 B1).

Au-Young et al. disclose a composition comprising at least a portion of a sequence selected from the group consisting of SEQ ID Nos: 1-1490 (col. 1, last paragraph), where it is noted that SEQ ID NO: 249 (Table 1 in col. 27-28) is identical to SEQ ID NO: 22 of the instant claim 6. Au-Young et al. disclose using the composition as a hybridizable array element in a microarray for monitoring the expression of a plurality of target polynucleotides and in the

diagnosis of cancer (col. 2, second paragraph). Au-Young et al. disclose using non-tumorous colon tissue and diseased colon tissue with cecal mass (phenotypic) (i.e. col. 87, line 30 and col. 90, third paragraph) to assess differences in gene expression between healthy and diseased tissues or cells by analyzing changes in expression pattern for disease where the genes code for different polypeptides (col. 1, fourth paragraph and col. 11, seventh paragraph), detecting hybridization formation complexes including RNA transcripts and labeled binding proteins (col. 8, third to fifth paragraphs; col. 9, first paragraph; col. 10, third paragraph), and using expression profiles that can reflect the detectable levels of a plurality of target polynucleotides in a sample with a labeling moiety for detection for diagnosing cancer (col. 2, third paragraph), which represents comparing expression level of gene products of a test colon sample and a control sample which is indicative of a cancerous state of the test sample via detecting RNA transcript and protein levels, as stated in instant claims 6, 7, and 8.

Thus, Au-Young et al. anticipate instant claims 6-8.

Conclusion

No claim is allowed.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28,

1993) (See 37 CFR §1.6(d)). The Central Fax Center number for official correspondence is (571) 273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carolyn Smith, whose telephone number is (571) 272-0721. The examiner can normally be reached Monday through Thursday from 8 A.M. to 6:30 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang, can be reached on (571) 272-0811.

October 17, 2006

Carolyn Smith
Examiner
AU 1631